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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,227	03/05/2002	Richard R. Bott	GC723	8688

7590 11/01/2004

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EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/092,227

Applicant(s)

BOTT ET AL.

Examiner

Kathleen M Kerr

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 14-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Application Status***

1. In response to the previous Office action, a non-final rejection (mailed on May 14, 2004), Applicants filed a response and amendment received on August 16, 2004. Said amendment cancelled Claims 1-13, amended Claims 14 and 18, and added new Claims 19-22. Thus, Claims 14-22 are pending in the instant Office action and will be examined herein.

### ***Priority***

2. As previously noted, no claims to priority for previous applications have been requested in the instant application.

### ***Compliance with the Sequence Rules***

3. In response to the previous Office action, Applicant filed a substitute paper copy of the sequence listing. While a statement under 37 C.F.R. § 1.1821 has been placed in the file, said statement is unsigned. Thus, the instant application still does not comply with the sequence rules. Applicant is required to state, under signature, that the paper copy filed on August 16, 2004 is identical to the computer readable form filed on July 30, 2002 and that no new matter has been added.

### ***Withdrawn - Objections to the Specification***

4. Previous objection to the specification because the title is not descriptive of the elected species to which the claims have been limited to herein is withdrawn by virtue of Applicant's amendment to the title.

Art Unit: 1652

5. Previous objection to the Abstract for not completely describing the disclosed subject matter is withdrawn by virtue of Applicant's amendment.

***Withdrawn - Claim Objections***

6. Previous objection to Claims 14 and 18 for having arduous claim structure is withdrawn by virtue of Applicant's amendment to said claims.

***New - Claim Objections***

7. Claims 14 and 18 are objected to for having improper structure. An ---and--- must come between the final two steps of the methods. Correction is required.

***Withdrawn - Claim Rejections - 35 U.S.C. § 112***

8. Previous rejection of Claims 14-18 under 35 U.S.C. § 112, second paragraph, as being indefinite for the iteration step is withdrawn by virtue of Applicant's amendment.
9. Previous rejection of Claims 14-18 under 35 U.S.C. § 112, second paragraph, as being indefinite for the terms "three-dimensional rendition" and "three-dimensional model" is withdrawn by virtue of Applicant's amendment.

***New - Claim Rejections - 35 U.S.C. § 112***

10. Claims 18, 21, and 22 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claim 18, two steps "d" appear. Clarification is required.

Art Unit: 1652

11. Claims 19-22 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Since the final step in Claims 14 or 18 is an iteration step requiring one more round of screening, repeating all of the steps is confusing. Perhaps just repeating the final step in each claim is indicated. Moreover, for Claims 20 and 22, it is unclear what the “selected variant” is. Clarification is required.

***Maintained - Claim Rejections - 35 U.S.C. § 102/103***

12. Previous rejection of Claims 14-15 and 17 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Poulouse (USPN 5,352,594) in view of Short (USPN 6,171,820, see IDS) is maintained. Claims 19-20 are added to the instant rejection. Applicant’s arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicant argues, “there is no teaching ... of using structural data obtained from structural analyses (i.e., 3-D rendition) of a parent enzyme to identify residues for site-saturation mutagenesis”; the Examiner disagrees. Firstly, a 3-D rendition need not be any other than conceptualizing the “structure” of the enzyme in three-dimensional space. In other words, considering its linear sequence alone is insufficient since this is two-dimensional. But considering all residues within 15 angstroms of the active site is clearly a three-dimensional analysis, despite the fact that the data on which it is based is two-dimensional. All other method steps are clear from the disclosure as previously noted:

“Poulouse teaches a method for making mutant enzymes with altered substrate activities (see Abstract). A preferred enzyme is cutinase from *P. mendocina* whose sequence (see columns 4-5, bridging) is a truncated form of

Art Unit: 1652

Applicant's SEQ ID NO:1. Selection of mutation site(s) is performed by choosing residues within 15 angstroms of the active site or at positions within 6 amino acids of active site residues (see column 5). In the examples of Poulouse, identification of the active site (the catalytic triad) of the cutinase was performed using sequence homology to known serine hydrolases with known 3D structures (see columns 9-10). Poulouse teaches producing mutants and assaying for activity (see column 6, lines 23-39 and columns 11-20, Tables). Poulouse also teaches saturating selected sites on the enzyme to achieve the best results (see column 6, lines 40-47) and teaches "substitutions at more than one site within the parameters of the invention ... in order to **further optimize** the results" (emphasis added) (see column 6, lines 47-49). Thus, Poulouse teaches an iterative process as required by the instant claims."

Inherent in the steps of Poulouse are grading mutants and producing feedback; such steps are required to "further optimize" the produced variant cutinase. Thus, Poulouse anticipates the claims as previously stated.

In view of Applicant's arguments, Short need not be addressed because the anticipatory nature of Poulouse is maintained. Short does not anticipate the claims, but was used in the alternative that the disclosure of Poulouse was not considered to teach an iterative process. Applicant further argues obviousness using Short in that the Examiner used impermissible hindsight reconstruction, did not supply facts, etc. However, none of these remarks point to a particular assessment made by the Examiner in the rejection of record. The Examiner previously provided appropriate obviousness and motivation to include the iterative process of Short; however, as noted above, these arguments do not overcome the anticipation by Poulouse.

13. Previous rejection of Claims 16 and 18 under 35 U.S.C. 103(a) as being unpatentable over Poulouse (USPN 5,352,594) in view of Abo *et al.* (WO 00/34450) and optionally in view of Short (USPN 6,171,820, see IDS) is maintained. Claims 21-22 are added to the instant rejection.

Art Unit: 1652

Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicant argues that the teachings of Poulouse, Abo *et al.*, and Short, taken alone or in combination, would not result in the claimed invention. The Examiner disagrees for the reasons maintained above for the 102/103 rejection, specifically the anticipatory nature of Poulouse. Moreover, Abo *et al.* provides a reasonable expectation of success in producing thermostable variants as well as variants with different substrate activities like those of Poulouse.

#### ***Summary of Pending Issues***

14. The following is a summary of the issues pending in the instant application:
- a) Claims 14 and 18 stand objected to for having improper structure.
  - b) Claims 18, 21, and 22 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for two steps "d".
  - c) Claims 19-22 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.
  - d) Claims 14-15, 17, and 19-20 stand rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Poulouse (USPN 5,352,594) in view of Short (USPN 6,171,820, see IDS).
  - e) Claims 16, 18, 21, and 22 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Poulouse (USPN 5,352,594) in view of Abo *et al.* (WO 00/34450) and optionally in view of Short (USPN 6,171,820, see IDS).

#### ***Conclusion***

15. Claims 14-22 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Art Unit: 1652


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Kathleen M Kerr  
Primary Examiner  
Art Unit 1652

October 26, 2004